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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,939	11/14/2000	Conor Mulrooney	7146-106	1308

7590

07/01/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

15

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,939

Applicant(s)

MULROONEY, CONOR

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 14) filed on March 17, 2003 has been entered.
2. New claims 25-26 are added. Thus claims 1-18, and 20-26 are pending in this office action and are considered for examination in this office action.

Response to Arguments

3. Applicant's response to the office action (Paper No.15) is fully considered and deemed persuasive in part.
4. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.14).
5. With reference to the rejection made in the previous office action under 103(a), Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the arguments and new grounds of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18, and 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleuziat et al. (USPN. 5,849,547) and in view of Walker et al. (EP 0 500 224).

Cleuziat et al. teach an isothermal method of amplification of a target nucleic acid (RNA and /or DNA) wherein Cleuziat et al. disclose that the method comprises (i) hybridizing a first and

Art Unit: 1637

second primer with first and second complementary nucleic acid fragments, with binding region at 3'-ends of the said target nucleic acid fragments (see column 9, lines 27-67, column 10, lines 1-20, column 21, lines 29-57); (b) third and fourth primers having a degree of sequence homology with first and second primers and bind at their 3'- ends (column 10, lines 21-30 column 21, lines 29-57); (c, e) providing an enzyme having strand displacing polymerase activity and dNTPs, under conditions allowing hybridization, strand displacement polymerisation thereby producing an amplified amount of the first and second strands (see column 9, lines 47-55, column 12, lines 18-60, column 21, lines 29-57); Cleuziat et al. also disclose that the method also comprises (i) target nucleic acid from a single or double stranded DNA or RNA (see 21, lines 29-30); (ii) first and second primers comprise a length between 30 and 100 nucleotides, and third and fourth primers comprise a length ranging between 5 and 50 bases or nucleotides (see column 18, lines 26-31); (iii) the strand displacing DNA polymerase is selected from exonuclease deficient Klenow polymerase (see column 12, lines 4-11, lines 40-46); (iv) amplification includes the presence of further primers specific to other target sequences (multiplex amplification) or to all or some of the same target sequence (nested amplification) (see column 18, lines 26-56). However, Cleuziat et al. did not specifically teach the use of digestion resistant region of said target nucleic acid and use of an enzyme having 5'-double strand specific exonuclease activity.

Walker et al. ('224) teach a method for amplifying complementary first and second nucleic acid sequences each having a binding region at its 3' end wherein the method comprises (a) treating single stranded nucleic acid sequences with one or more primers (see column 10, lines 40-53) (in case of two primers, first primer hybridizes with first strand and the second

Art Unit: 1637

primer hybridizes with the second strand (see column 7, lines 18-25); (c and d) in the presence of a double strand specific exonuclease (see column 10, lines 40-53) and (e) modified deoxynucleoside triphosphates (dNTPs), allowing the reaction to proceed for a period of time sufficient to generate amplified reaction products (see column 10, lines 46-57). Wlaker et al. ('224) also disclose that (a) the modified or substituted dNTPS incorporated during amplification are resistant to digestion (see column 8, lines 36-43); (b) exonuclease used was T7 gene 6 exonuclease (see column 11, lines 45-46, and column 8, lines 46-53); other exonucleases useful for the method include lamda exonuclease, klenow fragment of DNA polymerase I and Bst polymerase (see column 8, lines 51-53, and column 9 lines 1-6); the primer length could be 15-100 nucleotides (see column 8, lines 15-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of amplification of single stranded nucleic acid sequences as taught by Cleuziat et al. with the method as taught by Walker et al. ('224) which is well known in the art at the time the invention was made, because Walker et al. ('224) states that "the instant method is readily applicable to the generation of multiple copies of a single strand nucleic acid sequence" (see column 10, lines 10-13). An ordinary practitioner would have been motivated to combine the method of Cleuziat et al. with the method of Walker et al. ('224) in order to achieve the expected advantage of a rapid and sensitive method for detecting a multiple complementary target sequences since incorporation of exonuclease digestion resistant region as taught by Walker et al. would improve the detection of many unknown complementary target nucleic acids.

Art Unit: 1637


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
June 16, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER